COMPRESSIBLE URETERAL STENT FOR COMFORT

Cross-Reference to Related Case

[0001] This application claims priority to and the benefit of the U.S. provisional patent application serial number 60/295,465, filed on June 1, 2001, the entirety of which is incorporated herein by reference.

Technical Field

[0002] This invention generally relates to ureteral stents. More particularly in one embodiment, the invention is directed to a ureteral stent having a bladder end adapted to reduce patient discomfort.

Background Information

[0003] A stent is a medical device provided for propping open an obstructed passage within the body, such as a blocked ureter. In general, ureteral blockage is a medical condition requiring treatment. A ureteral blockage can occur for a number of reasons, including the passage of a kidney stone and/or other material into the ureter where it becomes entrapped. Also, a tumor growing against the outer wall of the ureter can force compression or constriction of the ureter. A tumor on the internal ureteral wall can also cause blockage of the ureter. Ureteral stents are often used to correct such problems. A ureteral stent may be placed inside the ureter on a temporary basis to allow proper drainage of fluids from the kidney to the bladder. A ureteral stent usually comprises a straight length of hollow tubing with each end having a hook or a curl or other configuration for preventing migration or expulsion of the stent from its placed position within the ureter. One end of a typical ureteral stent is placed in the kidney and the other end is placed in the bladder. The end positioned in the kidney is typically configured to

retain the stent within the renal pelvis and to prevent the downward migration of the stent into the ureter. The bladder end of the stent is typically configured to prevent upward migration of the stent towards the kidney.

[0004] Figure 1 is a conceptual background drawing showing a portion of the human urinary tract. Referring to Figure 1, in a human urinary tract **100**, the ureters **102** and **104** transport urine from the kidneys **106** and **108** to the bladder **110**. The trigone region of the bladder **112** is located between the urethral opening **114** and the two ureteral orifices **116** and **118**. The pain associated with an in-dwelling ureteral stent is attributable in-part to contact between the stent and the bladder mucosa **120** in the trigone region **112**. The trigone region **112** is believed to be particularly innervated and sensitive to the presence of any foreign bodies such as the bladder end of a ureteral stent. The intramural tunnel regions **122** and **124** of the ureters **102** and **104**, respectively, act like valves, shutting off to prevent back flow of urine from the bladder **112** to the kidneys **106** and **108**. The intramural tunnel regions **122** and **124** are also believed to be particularly innervated and sensitive to the presence of any foreign bodies. In addition, further discomfort due to in-dwelling stents can be caused by flank pain due to urine shooting from the bladder **110** back up the ureters **102** and **104** intra-luminally via the stent, and/or extra-luminally around the stent.

Summary of the Invention

[0005] The invention generally relates to ureteral stents, particularly those that reduce (compared with conventional ureteral stents) patient discomfort when the stent is placed within the patient's body. One object of the invention is to keep the ureteral passage open to allow the flow of fluids from the kidney to the bladder. Another object of the

invention is to reduce, minimize or avoid patient discomfort associated with conventional in-dwelling ureteral stents by reducing irritation of the trigone region of the bladder mucosa.

[0006] In one embodiment, the invention is directed to a ureteral stent including an elongated portion, a retention portion for placement substantially within a kidney, and a collapsible portion for placement substantially within the intramural tunnel portion of a ureter and extending into the bladder. The elongated portion of the stent has a lumen which extends along the length of the ureter from the kidney to the bladder. According to one feature, the retention portion extends from a first end of the elongated portion and is configured to be retained within the kidney. According to another feature, the collapsible portion extends from a second end of the elongated portion, and it is collapsible under radial compression from the intramural tunnel region to inhibit back flow of urine to the kidney.

[0007] In one embodiment, the collapsible portion is fabricated from a mesh material. In another embodiment, the collapsible portion is fabricated from a wound coil. According to one feature, the collapsible portion includes an outer coating of a biocompatible material adapted to avoid tissue ingrowth. According to another feature, the collapsible portion includes an inner lining adapted to avoid urine encrustation on an inner surface of a lumen formed by the collapsible portion which extends from the lumen formed by the elongated portion of the stent.

[0008] In another aspect, the invention relates to methods of inserting into a patient one of the ureteral stents mentioned above. One method includes the step of passing a guide wire through the ureter and into the kidney. Thereafter, coaxially sliding a stent

over the guide wire and into the ureter by using a tubular stent pusher. One alternate method includes placing a stent with a closed kidney end over a guide wire, and then advancing the stent into the ureter by pushing the guide wire. According to another embodiment, the stent is inserted from the kidney downward through the ureter and into the bladder.

[0009] In yet other aspects, the invention features methods of manufacturing stents such as the ureteral stents mentioned above.

[0010] The foregoing and other objects, aspects, features and advantages of the invention will become more apparent from the following description and from the claims.

Brief Description of the Drawings

[0011] The foregoing and other objects of the invention and the various features thereof may be more fully understood from the following description when read together with the accompanying drawings in which like reference characters generally refer to the same parts throughout the different views and in which the depicted components are not necessarily drawn to scale:

[0012] Figure 1 is a schematic view of a human urinary tract;

[0013] Figure 2 is a schematic view of a ureteral stent according to an illustrative embodiment of the invention;

[0014] Figure 3A is a schematic view of a ureteral stent according to an illustrative embodiment of the invention, and positioned within a human urinary tract;

[0015] Figure 3B is a schematic view of the stent of Figure 3A, including an illustrative bladder end in a collapsed state;

[0016] Figure 4A is a longitudinal, cross-sectional view of the stent of Figure 2;

[0017] Figure 4B is a transverse, cross-sectional view of the stent of 4A, taken along the line A-A';

[0018] Figure 5A is an enlarged side view of an illustrative collapsible mesh portion of a stent of Figure 2, in an expanded and open state;

[0019] Figure 5B is a longitudinal, cross-sectional view of the illustrative mesh portion of the stent of Figure 5A, in an expanded and open state;

[0020] Figure 5C is a longitudinal, cross-sectional view of the illustrative mesh portion of the stent of Figure 5A, in a collapsed condition due to radial compression;

[0021] Figure 6A is a longitudinal, cross-sectional view of the illustrative mesh portion of the stent of Figure 5A, including an outer covering;

[0022] Figure 6B is a longitudinal, cross-sectional view of the illustrative mesh portion of the stent of Figure 5A, including an inner lining;

[0023] Figure 6C is a longitudinal, cross-sectional view of the illustrative mesh portion of the stent of Figure 5A, including both an inner lining and an outer covering;

[0024] Figure 7A is an enlarged side view of an illustrative collapsible wound coil portion of the stent of Figure 2, in an expanded and open state;

[0025] Figure 7B is a longitudinal, cross-sectional view of the illustrative wound coil portion of the stent of Figure 7A, in an expanded and open state;

[0026] Figure 7C is an enlarged side view of the illustrative wound coil portion of the stent of Figure 7A, in a collapsed state;

[0027] Figure 8A is a longitudinal, cross-sectional view, according to an illustrative embodiment of the wound coil portion of Figure 7A, including an outer covering;

[0028] Figure 8B is a longitudinal, cross-sectional view, according to an illustrative embodiment of the wound coil portion of Figure 7A, including an inner lining;

[0029] Figure 8C is a longitudinal, cross-sectional view, according to an illustrative embodiment of the wound coil portion of Figure 7A, including both an inner lining and an outer covering;

[0030] Figure 9 is a transverse, cross-sectional view of the mesh portion of Figure 4A, taken along the line B-B' in Figure 4A;

[0031] Figure 10A is a schematic view of the stent of Figure 2 having a J-shaped kidney retention portion, according to an illustrative embodiment of the invention;

[0032] Figure 10B is a schematic view of the stent of Figure 2 having a single loop shaped kidney retention portion, according to an illustrative embodiment of the invention; and

[0033] Figure 10C is a schematic view of the stent of Figure 2 having a multi loop shaped kidney retention portion, according to an illustrative embodiment of the invention.

Illustrative Description

[0034] As discussed above in summary, in one embodiment, the invention is directed to a ureteral stent having a bladder end adapted to reduce patient discomfort. Figure 2 depicts a ureteral stent **200** in accordance with an illustrative embodiment of the invention. Figures 3A and 3B depict the ureteral stent **200** placed inside a human urinary tract **100**. A skilled artisan will appreciate that a ureteral stent of the invention can be placed in either ureter **102** or **104**. However, for simplicity, the following discussion is limited to placement of the ureteral stent **200** within the ureter **102**. As depicted, the illustrative ureteral stent **200** includes an elongated portion **202**, a retention portion **204**,

and a collapsible portion **206**. The elongated portion **202** has a length **208** that is sufficient to extend through the ureter **102** from the kidney **106** to the bladder **110**. The elongated portion **202** of the ureteral stent **200** defines a lumen (shown in Figures 4A and 4B at **400**) extending from a kidney end **212** to a bladder end **214**. According to the illustrative embodiment, the ureteral stent **200** also includes one or more through apertures or eye ports **210** located along the length of the elongated portion **202** for providing fluid communication between an outer wall (shown in Figures 4A and 4B at **412**) and an inner lumen wall (shown in Figure 4B at **410**) to further enable drainage through the internal lumen **400** of the ureteral stent **200**. According to one feature, the elongated portion **202** is made of a physiologically compatible material such as, for example, polyvinyl alcohol, polyethylene oxide, hydroxy ethyl cellulose, stainless steel, or the like.

[0035] The retention portion **204** extends from the kidney end **212** of the ureteral stent **200**, and is adapted for placement substantially within the kidney **106**, and for retention of the placement. According to one feature, the retention portion **204** includes one or more through apertures or eye ports **211** for providing fluid communication between an outer wall (shown at Figure 4A at **414**) and an inner lumen (shown in Figure 4A at **402**) to further enable drainage through the internal lumens **400** and **402**.

[0036] The collapsible portion **206** extends from the bladder end **214** of the ureteral stent **200**, and is adapted for residing substantially within the intramural tunnel region **122** of the ureter **102** and for extending into the bladder **110**. According to an illustrative embodiment, the invention addresses reflex prevention and intramural tunnel irritation via the collapsible portion **206** of the ureteral stent **200**.

[0037] Figure 3A depicts the intramural tunnel region **122** in a relaxed state and the collapsible portion **206** of the ureteral stent **200** in an expanded and open state. As shown in Figure 3B, as the intramural tunnel region **122** contracts radially, the collapsible portion **206** collapses to restrict urine back flow from bladder **110** to the kidney **106**.

[0038] Figure 4A is a schematic of a longitudinal, cross-sectional view of the ureteral stent **200**. Figure 4B is a lateral cross-sectional view of the length **208** of the elongated portion **202** taken along the view A-A'. As mentioned above, and as shown in Figures 4A and 4B, the elongated portion **202** of the ureteral stent **200** defines an internal lumen **400** that extends through the elongated portion **202** between the kidney end **212** and the bladder end **214**. The retention portion **204** also defines an internal lumen **402** which extends from the lumen **400** of the elongated portion **202**. The retention portion **204** includes at least one through aperture **404** adapted for providing fluid communication between the internal lumen **402** and the kidney **106**.

[0039] The collapsible portion **206** also defines an inner lumen **406** which extends from the internal lumen **400** of the elongated portion **202**. The inner lumen **406** terminates in at least one through aperture **408**. As shown in Figures 3A and 3B, when placed in a patient, the through aperture **408** resides within the bladder **110** and is adapted for providing urine flow from the lumen **406** into the bladder **110**.

[0040] Figure 5A depicts one illustrative embodiment in which the collapsible portion **206** of a ureteral stent **200** of the invention includes a mesh portion **500**. Illustratively, the mesh portion **500** extends from the bladder end **214** of the elongated portion **202**. In Figure 5A, the mesh portion **500** is depicted in an expanded and open state. Figure 5B is a longitudinal, cross-sectional view of the collapsible portion **206** of

the stent of Figure 5A in the expanded and open state. As shown, the mesh portion **500** forms an inner lumen **502** which extends from the internal lumen **400** of the elongated portion **202**. The lumen **502** ends in at least one opening **504** which resides in the bladder **110** to allow fluid communication between the lumen **502** and the bladder **110**. Figure 5C is a longitudinal, cross-sectional view of the collapsible mesh portion **500**, shown in a collapsed state. As discussed above, the collapsible portion **206** collapses, for example, due to a radial force exerted on the exterior of the mesh portion **500**, and inhibits through fluid flow. In one illustrative embodiment, the mesh portion **500** is manufactured from polymeric or metallic materials such as, for example, stainless steel, tantalum, gold, titanium, nitinol, polytetrafluoroethylene (PTFE) or any suitable material that collapses under an exerted force of the type exerted by the intramural tunnel region **122** of the ureter **102**, and returns to an expanded state upon removal of such a force. One advantage of the invention is that the collapsible mesh portion **500** of the ureteral stent **200** prevents fluid flow in response to radial force exerted by the intramural tunnel region **122** by collapsing to inhibit vesicourinal reflux, back flow of urine and flank pain in a patient.

[0041] Figures 6A-6C depict enlarged longitudinal, cross-sectional views, further illustrating embodiments of the mesh portion **500**. As shown in Figure 6A, in one illustrative embodiment, the collapsible mesh portion **500** has an outer covering **600**. In the illustrative embodiment, the outer covering **600** is formed from a flexible polymer such as, for example, polyurethane, polyamide, silicone, polyvinyl chloride, or the like. As shown in Figure 6B, in a further illustrative embodiment, collapsible mesh portion **500** has an inner lining **602** such as, for example, a jacket or a sleeve. In one

embodiment, the inner lining **602** encases the interior of the mesh portion **500**. The inner lining **602** functions to substantially prevent internal mesh encrustation due to urine contact. In the illustrative embodiment, the inner lining **602** is fabricated from a polymer such as, for example, polyurethane, polyamide, silicone, polyvinyl chloride, or the like.

[0042] In one preferred embodiment, the collapsible mesh portion **500** includes both an outer covering **600** as well as an inner lining **602**. In the illustrative embodiment, the mesh portion **500** is sandwiched between an outer covering **600** and an inner lining **602**, which encase the exterior and the interior of the mesh portion **500** respectively. In another embodiment, a polymer is interspersed within the mesh.

[0043] Figures 7A-7C depict an alternative embodiment in which the collapsible portion **206** of the ureteral stent **200** includes a wound coil **700** instead of a mesh portion **500**. The wound coil **700** behaves similarly to the mesh portion **500**, in that under radial force from the intramural tunnel region **122** of the ureter **102**, the wound coil **700** flattens out to close off the lower portion of the ureter **102** and thus prevent urine back flow to the kidney **106**. Figure 7A depicts one illustrative embodiment in which the wound coil **700** extends from the bladder end **214** of the elongated portion **202**. In Figure 7A, the wound coil **700** is depicted in an open and expanded state. Figure 7B is a longitudinal, cross-sectional view of the collapsible portion **206** of the ureteral stent of Figure 7A in an open and expanded state. As shown, the wound coil **700** forms a lumen **702** which extends from the internal lumen **400** of the elongated portion **202**. Figure 7C is an illustrative embodiment featuring the wound coil **700** in a collapsed state. As discussed above, the wound coil **700** collapses, for example, due to radial force exerted on the exterior of the

wound coil **700** and inhibits fluid flow through the lumen **702**. In response to the radial force being removed, the radial wound coil **700** returns to the expanded and open state. .

[0044] Figures 8A-8C depict enlarged longitudinal cross-sectional views, further illustrating embodiments of the wound coil **700**. As shown in Figure 8A, the collapsible wound coil **700** has an outer covering **800**. In an illustrative embodiment, the outer covering **800** is formed from a flexible polymer such as, for example, polyurethane, polyamide, silicone, polyvinyl chloride, or the like. As shown in Figure 8B, in a further illustrative embodiment, the wound coil **700** has an inner lining **802**, such as, for example, a jacket or a sleeve. In one embodiment, the inner lining **802** encases the interior of the lumen **702** of the wound coil **700**. In the illustrative embodiment, the inner lining **802** is fabricated from a polymer such as, for example, polyurethane, polyamide, silicone, polyvinyl chloride, or the like.

[0045] In one preferred embodiment of the invention, the wound coil **700** includes both an outer covering **800** as well as an inner lining **802**. In the illustrative embodiment, the wound coil **700** is sandwiched between an outer covering **800** and an inner lining **802**, which encase the exterior and the interior portions of the wound coil **700** respectively.

[0046] Figure 9 is an enlarged, transverse cross sectional end view of the terminal end **416** of the collapsible portion **206** taken along view B-B'. In one preferred embodiment, the collapsible portion **206** has a polymeric ring **900** extending circumferentially around its terminal end **416**. According to the illustrative embodiment, the polymeric **900** ring protects, for example, the jagged edges of the mesh portion **500** or wound coil **700** and helps to maintain the shape of the mesh portion **500** or wound coil portion **700** after the ureteral stent **200** is placed within a patient. Preferably, the

polymeric ring **900** is made from a thermoplastic polymer. In yet another embodiment, a retention flange is used instead of a polymeric ring.

[0047] Figures 10A-10C are conceptual drawings depicting various illustrative embodiments of the retention portion 204. The retention portion 204 of the ureteral stent 200 may be shaped, for example, as a hook, a coil or a malecot, or the like, to facilitate its retention in the kidney 106. In one illustrative embodiment, shown in Figure 10A, the retention portion 204 of the ureteral stent 200 is shaped like a J hook 1000. In another illustrative embodiment, shown in Figure 10B, the retention portion 204 of the ureteral stent 200 has a single loop configuration 1002. In a preferred illustrative embodiment of the invention, depicted in Figure 10C, the retention portion 204 has a multi-loop configuration 1004. In this illustrative embodiment, the multi-loop configuration 1004 allows the ureteral stent 200 to compensate for any changes in the length of the ureter 102 caused by peristalsis in the urinary tract 100. The multi-loop configuration 1004 also enables the accommodation of different ureteral sizes in different size patients.

[0048] Various methods are used for inserting the ureteral stent **200** into a patient. In one embodiment of the invention, the retention portion **204** of the ureteral stent **200** is inserted though the urethral opening **114** of a patient, advanced through the bladder **110** and the ureter **102**, and subsequently placed in the kidney **106** of the patient. Prior to insertion, the collapsible portion **206** is temporarily collapsed to facilitate insertion into the patient's body. The retention portion **204** is also straightened out prior to insertion.

[0049] In yet another embodiment of the invention, a cytoscope is used for inserting the ureteral stent **200** of the invention into a patient. In this embodiment, the ureteral stent **200** is inserted within the cytoscope prior to insertion into the urinary tract **100** and

the cytoscope is removed subsequent to proper positioning of the ureteral stent **200** within the patient.

[0050] In yet another embodiment, the mesh portion **500** of the ureteral stent **200** is maintained to have a sufficiently large inner diameter, so as to allow passage over a guide wire.

[0051] In one aspect of the invention, a method of manufacturing the collapsible mesh portion **500** of the ureteral stent is **200** described. The mesh portion **500** is fabricated from polymeric or metallic materials, such as, for example, stainless steel, tantalum, gold, titanium, nitinol, polytetrafluoroethylene (PTFE) or any suitable plastic material that is collapsible when formed and radially expandable.

[0052] The mesh portion **500** can be of any design or configuration and is made in any manner described in the art. In one embodiment of the invention, the mesh is braided in a "2 over-2 under" helical pattern. The mesh braid is then laminated over the bladder end **214** of the elongated portion **202** of the ureteral stent **200**.

[0053] In another embodiment, individual mesh strands are attached to each other via thermal bonding, in the case of polymeric materials, or via resistance welding or use of an adhesive in the case where metallic elements are utilized.

[0054] In yet another embodiment, the braided mesh is braided directly over the bladder end **214** of the ureteral stent **200** using a pre-heat step to embed the braid onto the bladder end **214**. In another aspect of the invention, ureteral stent **200** is prepared by hollowing out a metal pipe to leave a stent skeleton. Exemplary processes known in the art for preparation of the ureteral stent **200**, include an etching process, also known as photo-fabrication; processes that employ masks and chemicals; electric discharge

machining processes; and mechanical machining processes or stamping an open-cell pattern into a solid tube which is usually made of a polymeric material.

[0055] A ureteral stent **200** is used to treat ureteral blockage for proper drainage of fluids between the kidney **106** and the bladder **110**. Treatment of ureteral blockage is provided, for example, by inserting a ureteral stent **200** over a guide wire with a pusher through the urethral opening **114** and into the bladder **110**. The guide wire or a cannula is used temporarily to straighten out the retention portion **204** of the ureteral stent **200**. The retention portion **204** of the uretral stent **200** is typically made from material that is able to regain its structure after distortion which allows for the retention portion **204** to be straightened out prior to placement within the body.

[0056] In one aspect of the invention, a method for treating ureteral blockage in a patient includes sliding the ureteral stent **200** over a guide wire. The guidewire is inserted into the body of a patient through the bladder **110** and into the ureter **102**. A ureteral stent **200** is subsequently slid over the guide wire, such that one end of the guide wire is inserted through the kidney end **212** of the ureteral stent **200**. The ureteral stent **200** is moved along the length of the guide wire by the use of a pusher which includes a lumen to accept a guide wire.

[0057] In a preferred embodiment of the invention, the collapsible mesh portion **500** maintains a sufficiently large inner diameter so as to allow passage over a 0.035" / 0.038" guide wire. In one embodiment, the ureteral stent **200** is tracked over the wire for positioning inside the body using conventional methods of placement such as a pusher to abut the retention portion **204** of the ureteral stent **200**.

[0058] Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill in the art without departing from the spirit and the scope of the invention. This invention is not limited to the preceding illustrative description.

[0059] What is claimed is: